

CLAIMS

1. An axle of a rotatable element of an actuation indicator, wherein the axle is provided by a spring that is adapted in use to bias the rotatable element towards another element of the actuation indicator with which the rotatable element is engaged.
2. The axle of claim 1, wherein the rotatable element is a pinion.
3. The axle of claim 2, wherein the other element with which the pinion engages is a rack.
4. The axle of claim 1, wherein the rotatable element is an indicator wheel for indicating actuation of a device with which the indicator is associated.
5. The axle of claim 4, wherein there are at least two rotatable elements on the same axle.
6. The axle of claim 4 or 5, wherein the other element is a rotatable element mounted on a second axle, the second axle optionally being provided by the spring.
7. An assembly comprising the axle of any one of claims 1-6, the or each rotatable element on the axle and the other element.
8. The axle of claim 6, wherein the spring comprises the second axle and a biasing section connecting the two axles to bias them together.
9. An actuation indicator comprising a drums sub-assembly comprising a rotatable actuation indicator wheel, a rocking,

ratchet pawl for rotating the indicator wheel in a set direction and a rocking mechanism for the pawl driven by a slipping clutch arrangement, wherein the slipping clutch arrangement comprises a slipping clutch spring engaged at one end to a pinion of a rack and pinion assembly and at a second end to the ratchet pawl.

10. The actuation indicator of claim 9, wherein the slipping clutch spring has a generally U-shaped configuration.

11. The actuation indicator of claim 10, wherein the open end of the spring engages a boss of the pinion and the closed end of the spring defines a track for slidably engaging a boss provided on the pawl.

12. The actuation indicator of claim 9, 10 or 11, wherein the ratchet pawl engages a ratchet wheel that is fixed to the indicator wheel.

13. The actuation indicator of claim 12, wherein a resilient, non-return leg engages a tooth of the ratchet wheel to prevent rotation of the ratchet wheel in a direction other than the set direction, and the non-return leg rides up and over the teeth to allow rotation in the set direction.

14. The actuation indicator of any one of claims 9 to 13, wherein there are at least two indicator wheels arranged to sequentially count down from a set figure to zero, wherein the indicator wheels lock from further rotation in the set direction when they have counted down to zero, the slipping clutch spring then slipping on further attempts to rotate the mechanism.

15. A casing adapted to be attached over a valve stem end of a canister to form a canister unit, the casing comprising a sleeve part having a generally cylindrically shaped section having a generally cylindrical inner surface
5 extending from a top of the sleeve part towards a base wall, and a collar affixable around a neck of the canister, and sized, when around the neck of the canister, to fit through the top of the sleeve part, into the sleeve part, whereat it will contact at least a portion of the generally cylindrical
10 inner surface, wherein the generally cylindrical inner surface has a shoulder for supporting the collar to prevent the collar from being inserted further into the sleeve part, the shoulder being spaced from the top and the base wall of the sleeve part.
- 15 16. The casing of claim 15, wherein the top of the sleeve part comprises a chamfered surface to assist with the insertion of the collar into the sleeve part.
17. The casing of claim 15 or claim 16, wherein the shoulder is formed by an annular step in the generally
20 cylindrical inner surface.
18. The casing of claim 15 or claim 16, wherein the shoulder is formed by a ledge attached to the generally cylindrical inner surface.
19. The casing of any one of claims 15 to 18, wherein the
25 collar is a split ring collar.
20. The casing of any one of claims 15 to 19, wherein the collar, in an assembled canister unit, is welded to the sleeve part.

21. A casing adapted to be attached over a valve stem end of a canister to form a canister unit, the casing comprising a sleeve part for receiving a canister and a cap part for receiving a counter assembly of a dose counter for the
5 canister unit, wherein the cap part and counter assembly can be assembled together separate from the sleeve part and canister, the sleeve part and cap part then being joinable together to form the casing.

22. The casing of claim 21, further comprising a counter
10 assembly, the counter assembly comprising a drums sub-assembly.

23. The casing of claim 21 or 22, further in accordance with any one of claims 15 to 20.

24. The casing of claim 21, 22 or 23, wherein the sleeve
15 part is adapted to receive more than one form of valve stem end.

25. The casing of claim 24, wherein the sleeve part comprises a top through which, in use, a valve stem end of the canister will be inserted and a base wall spaced from
20 the top having more than one support thereon, each support adapted to support a different form of valve stem end, whereby more than one valve stem end is supportable in the sleeve part.

26. The casing of claim 25, wherein the supports are
25 annular ledges.

27. The casing of claim 26, wherein the ledges are concentric.

28. The casing of any one of claims 25 to 27, wherein a first support is of a first height above the base wall and the second support is of a lesser height above the base wall.

5 29. Components for the casing of any one of claims 15 to 28, comprising a cap part and at least two sleeve parts, the two sleeve parts being for different forms of valve stem ends, wherein the cap part is joinable to any one of the sleeve parts to form a casing for a chosen valve stem end.

10 30. A sleeve part for receiving a valve stem end of a canister, the sleeve part being adapted to receive more than one form of valve stem end.

31. The sleeve part of claim 30, wherein the sleeve part comprises a top through which, in use, a valve stem end of
15 the canister will be inserted and a base wall spaced from the top having more than one support thereon, each support being for supporting a different form of valve stem end, whereby more than one form of valve stem end is able to be supported in the sleeve part.

20 32. The sleeve part of claim 31, wherein the supports are annular ledges.

33. The sleeve part of claim 32, wherein the ledges are concentric.

34. The sleeve part of any one of claims 31 to 33, wherein
25 a first said support is of a first height above the base wall and a second said support is of a lesser height above the base wall.

35. A drug product for dispensing a drug formulation comprising a propellant and a medicament comprising:

a housing;

a container containing the drug formulation having an
5 outlet member and

adapted to be actuable within the housing; and,

an actuation indicating assembly, fixedly attached to the container, comprising:

a body cradle having a post;

10 a drive wheel adapted to engage the post and to frictionally engage a slipping clutch;

a ratchet pawl adapted to engage the slipping clutch;

a star wheel adapted to engage the ratchet pawl; and

one or more drums adapted to engage the star wheel;

15 wherein the fixedly attached container and actuation indicating assembly are reversibly removable from the housing as a single unit.

36. The drug product of claim 35, comprising three drums adapted to display a count of 000 to 999, and further
20 comprising an arm affixed to a hundred's drum adapted to contact a stop, wherein the slipping clutch is adapted to frictionally slip when the count reaches 000.

37. The drug product of claim 35, comprising a hundred's drum having numerals 0, 1 and 2, a ten's drum having
25 numerals 0 through 9 and a one's drum having numerals 0 through 9.

38. The drug product according to claim 35, 36 or 37, wherein the actuation indicating assembly includes one or more grip members adapted to fixedly engage a neck portion of the container.
- 5 39. The drug product according to any one of claims 35 to 38, wherein the housing includes a mouthpiece.
40. The drug product according to claim 39, wherein the housing includes a passage adapted to pass doses from the container to the mouthpiece.
- 10 41. The drug product according to any one of claims 35 to 40, wherein the container includes a metering valve adapted to dispense metered doses.
42. The drug product according to any one of claims 35 to 41, further including a window adapted to display numerals
15 on one or more drums engaging the star wheel.
43. The drug product according to any one of claims 35 to 42, wherein the actuation indicating assembly is fixed to the container by an adhesive, a welded shrink sleeve, a heat form, a crimp, an ultrasonic weld, an o-ring elastomer, or a
20 split-ring collar.
44. The drug product of any one of claims 35 to 43, wherein the actuation indicating assembly is permanently fixed to the container.
45. The drug product of any one of claims 35 to 44, wherein
25 the medicament is selected from the group consisting of beclomethasone, fluticasone, flunisolide, budesonide, rofleponide, mometasone, triamcinolone, noscapine, albuterol, salmeterol, ephedrine, adrenaline, fenoterol,

formoterol, isoprenaline, metaproterenol, terbutaline, tiotropium, ipratropium, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimiterol, isoetharine, tulobuterol, (-)-4-amino-3,5-dichloro- α -{{{6-{2-(2-

5 pyridinyl)ethoxy}hexyl}methyl} benzenemethanol, esters, solvates and salts thereof, and combinations thereof.

46. The drug product of claim 45, wherein the medicament is albuterol sulphate.

47. The drug product of claim 45, wherein the medicament is
10 salmeterol xinafoate.

48. The drug product of claim 45, wherein the medicament is fluticasone propionate.

49. The drug product of claim 45, wherein the medicament is beclomethasone dipropionate.

15 50. The drug product of claim 45, wherein the medicament is the combination of salmeterol xinafoate and fluticasone propionate.

51. The drug product of claim 45, wherein the medicament is salmeterol xinafoate and a salt, ester or solvate of
20 ipratropium.

52. The drug product of any one of claims 35 to 51, wherein the housing is constructed from polypropylene.

53. The drug product of any one of claims 35 to 52, wherein one or more components of the actuation indicating assembly
25 are constructed from polypropylene.

54. The drug product of any one of claims 35 to 53, further comprising one or more knock gears adapted to engage the one or more drums.

55. The drug product of claim 54, comprising first, second
5 and third drums and first and second knock gears.

56. A method of patient compliance comprising the acts of:
providing the drug product of any one of claims 35 to
55,

administering the drug formulation to a patient,
10 counting down a number of available doses remaining in
the container on the actuation indicating assembly, and
indicating the number of available doses remaining in
the container to the patient.

57. The method of claim 56, wherein the container is over-
15 filled with up to 40 actuations.

58. The method of claim 56, wherein the actuation
indicating assembly locks out when the count reaches 000 and
the drug product remains actuatable for up to 40 subsequent
actuations.

20 59. A drug product for dispensing a drug formulation
comprising a propellant and a medicament comprising:

a housing;

a container containing the drug formulation having an
outlet member and adapted to be actuatable within the housing;
25 and

an actuation indicating assembly, fixedly attached to
the container, comprising:

a body cradle having a post;

a means for driving a slipping clutch means adapted to engage the post and to frictionally engage the slipping clutch means for grasping a ratcheting means;

5 a pawl means for ratcheting a star wheel adapted to engage the slipping clutch means;

a star wheel adapted to engage the pawl ratcheting means; and

one or more drums adapted to engage the star wheel;

10 wherein the fixedly attached container and actuation indicating assembly are reversibly removable from the housing as a single unit.

60. The drug product of claim 59, comprising first, second and third drums, and further comprising a means for stopping
15 the first drum.

61. The drug product of claim 59 or 60, further comprising a first means for knock locking the first and second drums, and a second means for knock locking the second and third drums.

20 62. The drug product of claim 59, 60 or 61, further adapted to indicate a count of 000 to 999, and further adapted to lock the drums when the count indicates 000.

63. A sleeve part substantially as hereinbefore described with reference to the accompanying drawings.

25 64. A casing substantially as hereinbefore described with reference to the accompanying drawings.

65. A pMDI substantially as hereinbefore described with reference to the accompanying drawings.

66. An actuation indicator substantially as hereinbefore described with reference to the accompanying drawings.

5 67. An axle assembly substantially as hereinbefore described with reference to the accompanying drawings.

68. An axle substantially as hereinbefore described with reference to the accompanying drawings.

69. A drug product substantially as hereinbefore described
10 with reference to the accompanying drawings.